

EDGE

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Rewards of Research

THE FIELD OF PROSTHETICS EXISTS TODAY
BECAUSE THERE HAVE ALWAYS BEEN
INNOVATIVE PEOPLE WHO BELIEVED IT
WAS POSSIBLE TO MAKE FUNCTIONAL
REPLACEMENT LIMBS.

Not surprisingly, some of the earliest creators of prosthetic components were people with limb loss who designed, and sometimes built, their own devices, including pioneers like Samuel Decker, a Civil War veteran with bilateral upper-limb loss, and D. W. Dorrance, who invented the split hook terminal device in 1912 after losing his hand in a sawmill accident.

Decades ago, these inventors and prosthesis users were among the first to practice evidence-based prosthetic care. Their direct experiences as prosthesis users served as the raw data—the relevant evidence—that informed and improved their prosthetic designs. In their own way, these self-made prosthetists modeled why it's impor-

tant for prosthetic providers to consistently collect and analyze real-time patient performance data.

As clinicians who specialize in holistic, upper-limb prosthetic rehabilitation, the focus at Arm Dynamics (AD) is to optimize patient outcomes through an evidence-based approach to care. Researching the best available evidence and applying it to refine each patient's prosthetic fit and functionality is at the heart of this approach. The patient data that we've been gathering and analyzing for more than ten years has generated a dynamic care model that is continuously improving.

Delivering excellent patient care that helps

people regain independence is the primary mission of prosthetic providers. But there are additional opportunities that underlie this work—the possibility of digging deeper to uncover rich patient data that can optimize patient outcomes and ignite research collaborations to advance prosthetic care.

ASSURANCE IS CENTRAL TO EVIDENCE-BASED CARE

Quality assurance (QA) assesses the quality of processes or services a patient receives. This includes evaluating current goals, identifying problem areas, and creating a path to resolve issues. Prosthetic providers who practice QA

know that when patients return home with a new prosthesis, their need for care and support continues for the rest of their lives.

In essence, QA involves following up with patients to collect feedback after they have received prosthetic care and been fitted with their devices. If the feedback indicates there may be issues with the use or wear of the prosthesis, the provider proactively addresses and seeks to resolve the problem.

Our clinical team relies on a range of QA tools, one of which is called the FIT Survey.



This short questionnaire is administered every three months for the life of the prosthesis. It's easy for a patient to complete, taking just one to two minutes.

The FIT Survey looks at five different domains to identify subtle changes in the fit of the prosthesis. These small shifts are something the patient may not be aware of, but that could impact their functional ability or reduce their prosthesis wear time.

Over time, the survey creates multiple data sets for each person. Every time a FIT Survey is returned, the clinical team has the opportunity to analyze changes and proactively contact the patient to schedule a follow-up appointment. By quickly identifying and correcting problems, patients will naturally increase prosthesis wear time and build confidence in their ability to use the devices.

With consistent use, interpretation, and follow-up, tools like the FIT Survey are efficient ways to improve patient outcomes.

COLLECTING PATIENT DATA

At AD, collecting patient data is the domain of the on-site clinical therapy specialist at each care center. Therapists and prosthetists work side by side, analyzing patient outcome data and using it to provide holistic rehabilitation that maximize patients' functional independence.

Therapists begin gathering data at the initial appointment with a screening tool called the Wellness Inventory. It helps identify psychosocial challenges such as pain, depression, resiliency, and substance abuse. The therapist reviews and scores each inventory to be aware of potential issues that could interfere with a patient's prosthetic rehabilitation. Based on the results of the inventory, the team may modify their approach or arrange for specialized services, such as the patient meeting with a mental health professional. By combining the data collected at all

our centers, we are able to identify which psychosocial issues are the most prevalent among this population and modify our care model to address them.

As prosthetic rehabilitation begins, patient outcome measures are the next opportunity to collect important baseline data. Historically, outcome measures administered to people with upper-limb loss were designed for much broader patient populations, including those with musculoskeletal and neurological disorders. Noting this gap in assessment tools for prosthetic patients, our clinical team decided to address the challenge of developing new outcome measures for people with upper-limb differences.

The inclusion of a full-time clinical therapy specialist at each of our centers has given us the capacity and experience to expand deeper

into research. Working in conjunction with the Food and Drug Administration (FDA) and the Defense Advanced Research Projects Agency, we created, tested, and validated two novel measures to be administered throughout the care process. One measure is performance based and the other is patient reported. Together, they capture a holistic perspective of a patient's prosthetic rehabilitation.

Both measures have been validated and published in peer-reviewed journals and are embedded within our care model. As a result, we have a significant data set that allows AD to create benchmarks predicated on amputation levels and prosthetic options. We can objectively identify whether or not patients have maximized their prosthetic rehabilitation potential. If not, we take concrete steps to address functional concerns and increase patient satisfaction. Our care model continues to evolve, which is the definition of an evidence-based practice.

Compiling patient data enables therapists and prosthetists to assess and improve care models and inform future prosthetic recommendations and development. Outcome measures apprise the treatment team and the patient of changes in status across the continuum of care and can identify when further prosthetic training or device modification are needed.

The Capacity Assessment of Prosthetic Performance for Upper Limb (CAPPFUL) is designed as a versatile, low-burden measure of prosthetic performance for any type of functional upper-limb prosthetic device and any level of upper-limb loss or absence.

Data from the CAPPFUL enables our clinicians to identify a patient's functional challenges and then modify the prosthetic design or treatment plan to improve outcomes. As a result, patients reach their maximum rehabilitation potential as quickly as possible.

Without this type of performance-based research, some may struggle with poor fitting prostheses or functional difficulties that limit their sense of well-being and personal independence.

The Comprehensive Arm Prosthesis and Rehabilitation Outcomes Questionnaire (CAPROQ) measures patient-reported outcomes in key facets of rehabilitation for adults with upper-limb loss or absence, including perceived function, satisfaction, and pain.

When viewed from a business perspective, there are additional benefits to doing research that can support an evidence-based care model in the following ways: ➔

- Objective outcome measures data can clearly demonstrate patient performance and satisfaction to referral sources and reimbursement agencies.
- Patient data sets that span six to ten years can attract funded research opportunities.
- Giving prosthetists and therapists the opportunity to engage in relevant research projects can support clinician retention.

COLLABORATIVE RESEARCH

Having access to years of relevant patient data can lead to interesting opportunities to engage with external researchers or organizations in connected fields. Our large number of patients with upper-limb amputations make it possible



An upper-limb prosthetic specialist and a clinical therapy specialist work collaboratively with every patient.

to facilitate research projects that achieve statistical relevance and capture a broad array of data.

Hundreds of our patients have participated in clinical trials and beta testing of components. Gerry Kinney, who has bilateral transradial amputations and eight years of experience using his prostheses, is eager to participate in clinical trials and product testing.

When patients participate in clinical trials, determining which outcome measures to use is important. In a peer-reviewed study from 2021, researchers and clinicians from the FDA, AD, and the University of Maryland School of Public Health examined patient performance (CAPPFUL and Box and Blocks) and patient-report measures (CAPROQ and Disabilities of the Arm, Shoulder, and Hand questionnaire) to assess if there is a correlation between performance and perceived function. It was found that there is no significant correlation, which supports the need for both types of outcome measures to gain a complete understanding of patients' functionality. The clinical team is then able to re-evaluate patients at any point

during care and modify the care plan as needed to maximize their rehabilitation potential.

In an associated 2021 study, the same team of researchers and clinicians assessed how different factors affect a patient's perceived function utilizing the CAPROQ. This patient-reported measure found that satisfaction, pain, and level of amputation were significantly associated with perceived function. This informs clinicians about potential factors to observe and continue assessing so that barriers to success can be mitigated.

INTERNAL RESEARCH

With the rapidly expanding market-place of prosthetic components and materials, patients

look to their prosthetic providers for up-to-date information on emerging technologies.

Our team regularly evaluates new components including hands, digits, wrist rotators, elbows, prosthetic liners, socket suspension systems, and cosmetic and decorative coverings. We record

our observations related to weight, durability, ease of use, speed, versatility, noise, and appearance.

If the team determines that a new component or accessory could be beneficial, we will invite one or more patients to field test it. Patients are selected for field testing based on a range of criteria that includes being a long-term, successful prosthesis user; having enthusiasm about trying new components and sharing feedback; proven dependability; and living in proximity to an AD center.

Amber Peterson began wearing a transradial prosthesis when she was an infant. Now a college freshman, her 18 years of using a prosthesis have included experience with myoelectric hands and a range of activity-specific devices. She

recently field tested a new electric hand.

Each patient who field-tests a new prosthetic component works with a clinical therapy specialist to complete outcome measure testing. We create a report for every component that we evaluate and include clinical observations and outcome measures data and scoring. We share this with our national clinical team and with the component manufacturer.

REWARDS OF RESEARCH

Building an evidence-based practice requires prosthetic providers to reach beyond the usual boundaries of clinical care. It calls for a larger team of clinicians, and a willingness to invest time, creativity, and effort in developing unique QA tools for patients.

By routinely asking patients to share key information during prosthetic care, clinicians can then analyze and apply this data to maximize each patient's rehabilitation potential. Aggregate patient data fuels a constantly evolving care model that can deliver objective and repeatable patient outcomes.

Collecting and analyzing individual patient data is the beginning, middle, and end of a true evidence-based practice. The rewards of research are clear: more dynamic and efficient care models, prosthesis users who thrive, opportunities for exciting collaborative research, and advances in the wider field of prosthetic care. **O&P EDGE**

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A bilateral upper-limb prosthesis user completes a performance-based outcome measure.